K082212

Special 510(k) Summary

1. Company Identification

Mallinckrodt Inc , Liebel-Flarsheim Business
2111 East Galbraith Road
Cincinnati, OH 45237

Establishment Registration 1518293

JAN 22 2009

2. Contact Person

Dale Moore
Quality Manager
Phone (513) 948-5771
Fax (513) 948-5708
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3. 510(k) Preparation Date

04/29/2008

4. Device Name

Trade Name Syringe with Handi-Fil
Common Name Syringe

5. Device Classification

Class II

6. Indications for Use

The Syringe with Handi-Fil is part of the contrast delivery system which is designed to inject radiopaque contrast media and/or saline into the vascular system for Angiographic or CT procedures as prescribed by qualified healthcare professionals

7. Description of Device

The proposed device is a disposable, single-use syringe, used to deliver radiographic contrast media and/or saline into a patient's vascular system for the purpose of obtaining enhanced diagnostic images The Syringe with Handi-Fil is plastic and consists of the same components as the predicate device The configuration is equivalent to other syringes already marketed by Mallinckrodt The syringe is provided to the customer packaged and sterilized

This submission covers the following devices 150 ml syringe with Handi-Fil
200 ml syringe with Handi-Fil

8. Substantial Equivalence

The term "Substantial Equivalence" as used in this 510(k) Premarket Notification submission is limited to the definition of Substantial Equivalence found in the Federal Food, Drug, and Cosmetic Act, 21 CFR § 807, Subpart E A determination of substantial equivalency under this submission is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters No

statements related to, or in support of, substantial equivalence in this submission shall be construed as an admission against interest under the US Patent Laws or their application by the courts

The predicate device to the Syringe with Handi-Fil is the syringe described in the premarket notification for Angiomat Illumena (K963071)

The Syringe with Handi-Fil maintains the same intended use as the predicate device It is intended to be used for the specific purpose of injecting radiopaque contrast media and/or saline into a patient's vascular system for Angiographic or CT procedures

Below is a table that compares the predicate device to the proposed Device

Feature	Syringe with Handi-Fil (New Device)	Angiomat Illumena Predicate Device (K963071)
Intended Use	The Syringe with Handi-Fil is part of the contrast delivery system which is designed to inject radiopaque contrast media and/or saline into the vascular system for Angiographic or CT procedures as prescribed by qualified healthcare professionals	The Angiomat Illumena is designed to inject radiopaque contrast media into the vascular system for Angiographic or CT procedures as prescribed by qualified healthcare professionals
Syringe Sizes	150 ml syringe with Handi-Fil 200 ml syringe with Handi-Fil	150 ml syringe with Handi-Fil 200 ml syringe with Handi-Fil
Sterility	Sterile, Single Use SAL – 10^{-6}	Sterile, Single Use SAL – 10^{-6}
Pressure Rating	150 ml syringe • 1200 psi – dynamic • 1300 psi – static 200 ml syringe • 300 psi – dynamic • 400 psi - static	150 ml syringe • 1200 psi – dynamic • 1300 psi – static 200 ml syringe • 300 psi – dynamic • 400 psi - static
Materials of Constructions	150 ml Syringe • polycarbonate • synthetic rubber • polyethylene • Polypropylene 200 ml syringe • polycarbonate • polypropylene • synthetic rubber • polyethylene Handi-Fil • Polyethylene	150 ml Syringe • polycarbonate • synthetic rubber • polyethylene • Copolyester 200 ml syringe • polycarbonate • polypropylene • synthetic rubber • polyethylene Handi-Fil • Polyethylene
Connectors	ISO 594-2 standard luer thread	ISO 594-2 standard luer thread

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mallinckrodt, Inc , Liebel-Flarsheim Business
c/o Mr Dale Moore
Site Quality Manager
2111 East Galbraith Rd
Cincinnati, OH 45237

JAN 22 2009

Re K082212
Trade/Device Name Syringe with Handi-Fil
Regulation Number 21 CFR 870 1650
Regulation Name Angiographic Injector and Syringe
Regulatory Class Class II
Product Code DXT
Dated December 19, 2008
Received December 22, 2008

Dear Mr Moore

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA) You may, therefore, market the device, subject to the general controls provisions of the Act The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898 In addition, FDA may publish further announcements concerning your device in the Federal Register

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820), and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474 For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464 You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address
http //www fda gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D Zuckerman, M D
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K082212

Device Name **Syringe with Handi-Fil**

Indications For Use

The Syringe with Handi-Fil is part of the contrast delivery system which is designed to inject radiopaque contrast media and/or saline into the vascular system for Angiographic or CT procedures as prescribed by qualified healthcare professionals

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Donna R. Whitney

(Division Sign-Off)
Division of Cardiovascular Device

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